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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,400	12/05/2003	Christopher L. Reading	202.14	9232

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EXAMINER	
KWON, BRIAN YONG S	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,400	READING ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25, 27, 38-48* is/are pending in the application.

4a) Of the above claim(s) *1-25,27 and 46-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-45* is/are rejected.

7)☒ Claim(s) *40 and 42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/2/06, 5/22/06, 5/18/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. By Amendment filed May 19, 2006, claims 26 and 28-37 have been cancelled and claims 38-45 have been newly added. Since the new claims 38-48 align with the original claims 30-37, the amendment is considered to be responsive to the Examiner's restriction requirement.

Applicants Response to Restriction Requirement Acknowledged

2. Applicant's election with the Group IV, treatment of graft rejection, along with 3β-hydroxy-5-androstene-17β-methylamine as the elected species is acknowledged. Claims 38-45 read on the elected invention.

Claims 1-25, 27 and 46-48 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claims.

3. It is noted that in the absence of any remarks or evidence to the contrary regarding the restriction and the election of single species requirement, the election is herein treated as an election without traverse.

Extension of Species Election

4. Examination of the present claims was performed herein to the extent that the claims read upon the use of the elected compound 3β-hydroxy-5-androstene-17β-methylamine for the elected method. A reasonable comprehensive search by the Examiner has determined that the use of such a compound for treating graft versus host rejection does not appear to be taught or suggested by the prior art.

For these reasons, the search and examination of the present claims has been extended to read upon the treatment of allogenic organ rejection using the compound defined by the formula,

known as 3β-1cetoxy-17β-(L-prolyl)-amino-5α-androstane. This corresponds to compound s of the present invention as defined in present claim 38, wherein: (a) one R1 is hydrogen and the other R1 is an ester; (b) one R2 is hydrogen and the other R2 is hydrogen; (c) both R3 together are hydrogen; (d) R4 is the alpha configuration is –NH-optionally substituted alkyl, and R4 in the beta configuration is hydrogen; (e) R5 is C1-C8 optionally substituted alkyl; (f) R6 is C1-C8 optionally substituted alkyl; (g) R7,R8 and R9 are each –C(R10)2, wherein R10 is hydrogen; (h) R10 is hydrogen; (i) R10B and R10C are each hydrogen; and further wherein each of the dotted lines represents a single bond.

Claim Objections

5. Applicant presents two identical claims 40. Claim 40 is objected to under 37 CFR 1.75 as being a substantial duplicate of another claim 40.

In addition, claim 40 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 42. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 38-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating or ameliorating allogenic tissue or organ rejection in patient having the allogenic rejection with the administration of said compound of the structure, does not reasonably provide enablement for a method of treating or ameliorating allogenic tissue or organ rejection in patient "that my be expected to experience the allogenic tissue or organ or cell population rejection". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The instant claims are drawn to a method for the therapeutic utility or prophylactic utility of using the compound of the structure for patient having allogenic tissue, organ, cell population rejection or patient at risk of having said condition.

The interpretation of the instant claim allows for the inclusion of prophylactic utility of said compound of the structure since the instant invention discloses that the patient group of the

instant invention (i.e., mammals) may be "expected to experience the allogenic tissue, organ or cell population rejection". The patient of the instant invention does not necessarily have to suffer from the condition. In other words, the scope of the instant invention encompasses the administration of said compound to the healthy mammal (free of the allogenic tissue, organ or cell population rejection at the time of the administration of the drug) to ameliorate the allogeneic tissue, organ or cell population rejection.

As discussed above, the treatment of patient expected to experience such condition, such a situation essentially amounts to, when interpreted in the broadest and most reasonable way, to the "prevention" of allogenic rejection. That is, in order to be enabled to practice the present invention by administering the claimed compound(s), the skilled artisan would have to accept that by administering the presently claimed compound(s), the incidence of the allogenic rejection would be zero and there would be a reasonable guarantee that such disease or disorder would never develop. However, the specification does not provide any competent evidence or disclosed tests that are highly predictive for the prophylactic utility of the instant compounds.

It is known today that the organ rejection is very difficult to treat and known that the treatment is not always successful ("Transplant Rejection", Medline Plus, www.nlm.nih.gov/medlineplus, 2006; "Transplant Rejection", www.chfpatietns.com, 2002). Furthermore, there are no known compounds of similar structure which have been demonstrated to prevent the allogenic tissue, organ or cell population rejection. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits as discussed above.

As discussed above, it is not understood how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to have the "prevention" or completely cure or eradication effect.

The specification discloses a huge and varied genus of compounds and that by employing any one of these compound that one may achieve the various condition including allogenic organ, tissue or cell rejection, hemorrhage, bone fracture, burns, lung fibrosis, cystic fibrosis and etc... The specification discloses potential assays methods in using the prophetic examples an "F1C" compounds (which has not explicitly identified) for the claimed utility (Example 22). However, there is no demonstrated correlation that the tests and results apply to the claimed preventive utility embraced by the instant claims.

The relative skill of those in the art of pharmaceuticals and the unpredictability of the pharmacy art is high. The skilled artisan would have not understood how to extrapolating the potential assay of using the prophetic examples to the claimed prophylactic utility without undue amount of experimentation.

Since the efficacy of the claimed compound(s) in "preventing" mentioned above disease cannot be predicted from a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 38-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Pettit et al. (US 2003/0216361 A1).

Pettit teaches the administration of 3β-1cetoxy-17β-(L-prolyl)-amino-5α-androstane (which reads on the instant compound of the structure) to mammals to treat bacterial infection (claims).

Although Pettit is silent about the prophylactic utility of said compound in preventing organ, tissue or cell population rejection, namely graft verus host disease, such prophylactic utility deems to be inherent the referenced method. The prior art directing administration of the same compound(s) inherently possessing the therapeutic effect as disclosed by Applicant anticipates the Applicant's invention. Applicant's attention is directed to Ex parte Novitski 126 USPQ 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a haec verba recitation for such prophylactic utility. In the instant case, as in Ex parte Novitski, the claims are directed to preventing a malady or disease with old and well known compounds of compositions. The prior art administering compounds inherently possessing a protective utility anticipates claims directed to such protective use.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 38-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 38-62 of copending Application No. 10/651,515 or claims 12-20 of copending Application No. 11/234,675. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed prophylactic utility of same compounds disclosed in the copending application deems to inherent to the referenced method.

As discussed above, The interpretation of the instant claim allows for the inclusion of prophylactic utility of said compound of the structure since the instant invention discloses that the patient group of the instant invention (i.e., mammals) may be "expected to experience the allogenic tissue, organ or cell population rejection". The patient of the instant invention does not necessarily have to suffer from the condition. In other words, the scope of the instant invention

encompasses the administration of said compound to the healthy mammal (free of the allogenic tissue, organ or cell population rejection at the time of the administration of the drug) to ameliorate the allogeneic tissue, organ or cell population rejection.

Since the copending applications directing administration of the same compound(s) inherently possessing the therapeutic effect as disclosed by Applicant anticipates the Applicant's invention, the copending applications make obvious the instant invention.

9. In looking in continuity data, it is noted that applicant has numerous issued patent or pending applications encompassing the same or similar subject matter of the instant application. Applicant should review all subject matter considered the same or similar, and submit the appropriate Terminal Disclaimer(s). For example, 10/949694, 10/606524, 10607035, 10/607415, 10/741929, 10/741929, 10/876957, 10/949782 and 10/877911 are considered to be same or similar subject matter(s).

Conclusion

10. No Claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

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